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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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[REDACTED] EXAMINER

SAUCIER, SANDRA E

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 02/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/585,821	Applicant(s) Halvorsen et al.
Examiner Sandra Saucier	Art Unit 1651

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Nov 15, 2001

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 835 C.D. 11; 453 O.G. 213.

4) Claim(s) 6-12 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 6-12 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s). _____

16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7,8 20) Other: _____

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DETAILED ACTION

Claims 6-12 are pending and are considered on the merits.

Information Disclosure Statement

The form 1449 submitted Aug. 9, 2001 is in the file. Unfortunately, the Patent Office has misplaced all of the references associated with this IDS before the file reached the examiner. A search was instituted for the misplaced references without positive results. Please resubmit the references in order that they be considered.

Claim Rejections – 35 USC § 112

NEW MATTER

Claims 6-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Insertion of the new claims 6-12 which have inadequate or no support in the as-filed specification is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limitations which would show possession of the concept at time of filing.

In the narrative portion of the specification, on page 4, in the "Summary of the Invention" where the broadest statement of the inventors' concept of the invention should be found, the invention is described as "a means to identify novel polypeptides secreted from human adipocytes into the conditioned medium", where the medium is described in the first paragraph and contains glucose, cyclic AMP inducer, glucocorticoid or analogue thereof, insulin or analogue thereof, a PPAR or RXR agonist. The methods of the invention as described in the first paragraph also require that at least 25,000 isolated, preadipocyte cells/cm² are plated. The original claim 6 was also narrower than the instantly claimed method. Please note that the instant method does not require that the polypeptides be secreted from adipocytes, but from a "differentiated preadipocyte" which may be broader than the original statement of "adipocyte". Further, the claim now requires that greater than 90% enriched population of isolated, differentiated, human preadipocytes be obtained prior to identifying a protein or peptide. Please point to the location in the specification

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where "greater than 90% enriched population" is found, as the examiner cannot find it. Further, the claimed method now includes the identification of a peptide. The narrative portion of the specification only mentions polypeptides, and example 7 only mentions proteins. Please note that the original claim only required fractionating the polypeptides while the instant claims now require identification of the polypeptides. Please do not broaden the original disclosure by claiming elements not supported at the very least by the broadest statement of invention in the specification. Applicants are not free to reconstruct and broaden their claimed invention after time of filing.

This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the instant claims are considered to be the insertion of new matter for the above reasons.

Please see *Gentry Gallery v. Berkline* 45 U.S.P.Q.2d 1498 for a discussion related to broadening the claimed invention without support in the as-filed specification. Please see *PurduePharma v. Faulding* 56 U.S.P.Q.2d 1481 for a discussion related to a failure to describe a claimed generic concept in the narrative portion of the specification, but rather basing support on limitations in examples.

Please carefully redraft the claimed method in order to avoid further new matter rejections and please point to the specific location in the specification where each of the elements of the claim are found. Assertions of general support are not evidence of support.

INDEFINITE

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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In claim 6, it is recited "obtaining a greater than 90% enriched population of isolated differentiated human preadipocytes". It is unclear if this phrase encompasses a culture of differentiated adipocytes no matter how obtained, because adipocytes are always the differentiated form of preadipocytes. Thus, an explant of mature adipocytes, put into a culture medium would appear to be encompassed by the claim. The intent of this recitation is unclear.

In claim 10, there is no antecedent basis for the plating of preadipocytes, since there is no culturing step in the independent claim.

Please note that the claims now pending require identification of the peptide or protein. However, it is unclear what this means. Would knowing the molecular weight be considered sufficient to identify the protein? Must one know the primary structure, the secondary structure, the tertiary structure and the function? "Identify" is an indefinite term without specification of the parameters used to identify the protein.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States, (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 6–8, 11 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Zilberfarb *et al.* [U].

The claims are directed to a method comprising obtaining a greater than 90% enriched population of isolated, differentiated, human preadipocytes, identifying a protein or peptide secreted by the enriched population.

The references are relied upon as explained below.

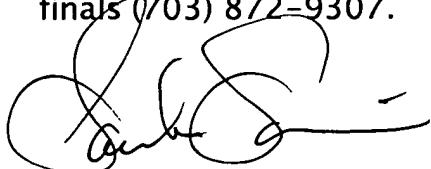
Zilberfarb *et al.* disclose a method whereby human preadipocytes are

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differentiated into adipocytes in the presence of medium which contains insulin and pioglitazone (Materials and Methods, page 802). Leptin is secreted by the differentiated cells (p. 806). Although the % of differentiated cells is not directly stated, as the method of differentiating the cells from preadipocytes to adipocytes is the same as the CLAIMED method of differentiating the cells, the result, that is, greater than 90% differentiated cells is reasonably assumed to be the same in the absence of evidence to the contrary. This should be an inherent result of the practice of the same method.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30AM to 6:00PM Tuesday-Friday and every other Monday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306 or for after finals (703) 872-9307.



Sandra Saucier
Primary Examiner
Art Unit 1651
February 21, 2002